

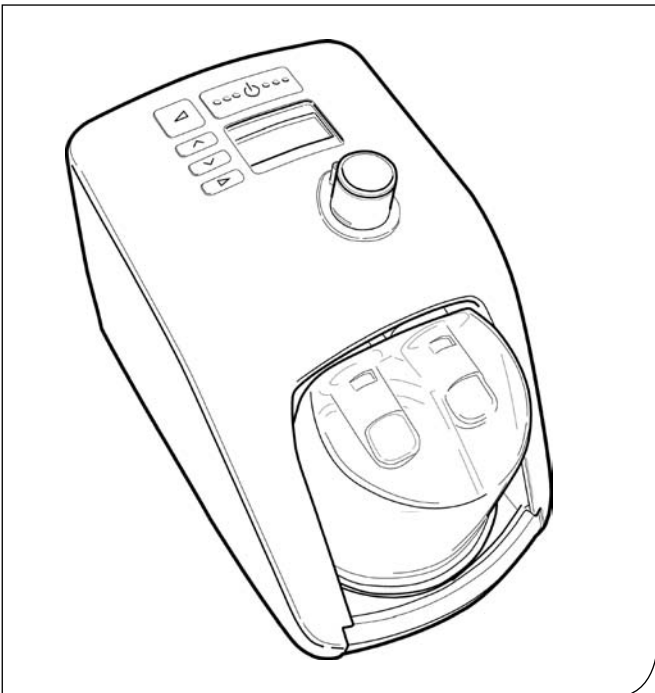
# *SleepStyle*<sup>™</sup>600

CPAP SERIES

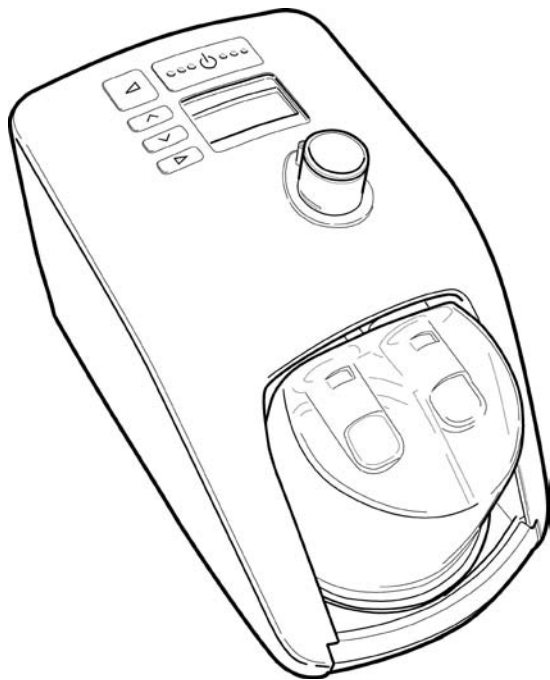
Thermo  
Smart®

## Operating Manual

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**Fisher & Paykel**  
HEALTHCARE



# SleepStyle™ 600

## CPAP SERIES

The SleepStyle™ 600 CPAP Series has integrated heated humidification and a heated breathing tube. It is designed for use in the home or sleep laboratory, for the treatment of Obstructive Sleep Apnea.

**For further assistance, please contact your local Fisher & Paykel Healthcare office – see back cover for details.  
Please keep this manual for future reference.**

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**PLEASE READ ALL INSTRUCTIONS BEFORE INITIAL USE**

Caution: USA Federal Law restricts this device for sale by or on the order of a physician.

# 1. SYMBOL DEFINITIONS

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Type BF  
Applied Part



ATTENTION  
Consult  
accompanying  
documents



IPX1  
Drip Proof



Alternating Current



Class II  
Double Insulated



Power  
On/Off

CE 0123

93/42/EEC  
Class IIb

## 2. INTENDED USE

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The device is used to assist with patient breathing while sleeping for the purpose of treating Obstructive Sleep Apnea (OSA). This is done by the delivery of Continuous Positive Airway Pressure (CPAP) in order to prevent airway obstruction. The addition of heated respiratory humidification to the device relieves the drying and irritating effects on the patient airways which usually arises from use of a CPAP system. The device is for use on adult patients at home or in the sleep lab. Please refer to the SleepStyle™ 600-Series product range listed in the appendix section of this manual.

## 3. WARNINGS

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**PLEASE NOTE:- This manual refers to the SleepStyle™ 600 CPAP Series unit as “the device”.**

1. The device should only be used with masks, connectors and delivery tubes recommended by Fisher & Paykel Healthcare, or by your physician or respiratory therapist.
2. Never operate the device if:
  - a) it has a damaged power cord or plug, b) the heated breathing tube has been damaged with holes, tears or kinks, c) it has been dropped or damaged, d) it has been dropped into water, e) it is not working properly, f) it is connected to a PC during CPAP treatment.Return the device to an authorised service center for examination and repair.
3. Do not use the device when the room temperature exceeds 35 °C (95 °F) as this may lead to an elevated airflow temperature which may give rise to an irritation of the airways.
4. Ensure an air filter is fitted when operating your unit.
5. Remove the humidification chamber before filling. Do not fill water through the heated breathing tube connection.
6. Do not fill the chamber with boiling water.
7. When handling or operating the device, avoid tipping the machine to prevent any chance of water entering the unit enclosure. If this does occur, immediately disconnect the power cord and discontinue use. Seek advice from your homecare provider.
8. Place your device on a level surface lower than your head height to prevent water entering the respiratory tubing should the device be knocked over.
9. Do not store or use your device where it can fall or be pulled into water. If water has entered the unit enclosure, disconnect the power cord and discontinue use. Seek advice from your homecare provider.
10. Never block the air openings of the device or place it on a soft surface such as a bed or couch, where the filter area may be blocked. Keep the air openings free of lint, hair or the like.
11. Ensure that the unit is dry before plugging into the power socket.
12. A mask should not be used unless the device is switched on, and operating properly. The vent hole(s) associated with the mask should never be blocked.
13. Due to the operating temperature of the heater plate, avoid making contact to the exposed heater plate or chamber base.
14. Ensure the water has cooled before emptying the chamber.
15. At low CPAP pressures, the flow through the mask may be insufficient to clear all exhaled gas from the tubing, and consequently some re-breathing may occur.
16. Adjusting the pressure control can result in ineffective therapy. The pressure control must only be adjusted by a healthcare professional.
17. Never drop or insert any object into any opening or heated breathing tube.
18. Always switch off the device and unplug the power cord from the power socket before cleaning.
19. Empty all the water from the chamber before transporting your device.
20. To remove the heated breathing tube, always push the sleeve up to avoid tube damage.
21. Refer all maintenance to qualified service personnel except as outlined in this manual.
22. Do not use an insulating sleeve or any similar accessories which are not approved by Fisher & Paykel Healthcare. These may affect the humidification performance.

## 4. OXYGEN USE WARNINGS

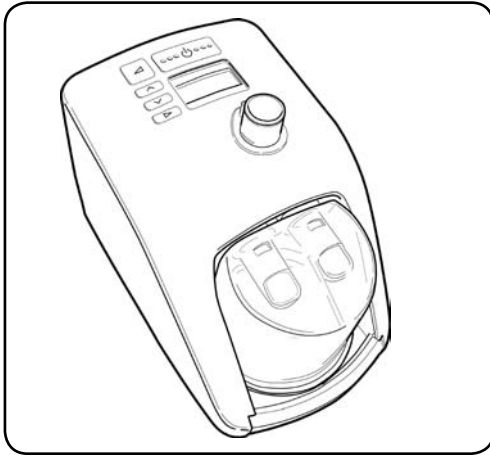
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If supplemental oxygen is used with the device, the oxygen flow must be turned off when the device is not operating. This ensures that oxygen will not flow through the heated breathing tube and accumulate in the device enclosure.

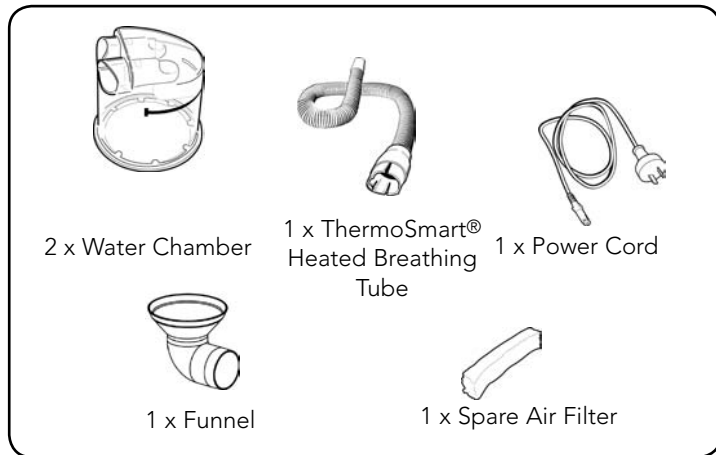
- The device should be located in a position where ventilation around the device is not restricted.
- It is recommended that supplemental oxygen be administered at the mask.
- Oxygen should not be used while smoking or in the presence of an open flame.
- The use of oxygen in therapy requires that special care be taken to reduce the risk of fire. Any materials which will burn in air and some that will not be easily ignited and burn rapidly in high concentrations of oxygen. Accordingly, for safety it is necessary that all sources of ignition be kept away from the product and preferably out of the room in which it is being used.
- A spontaneous and violent ignition may occur if oil, grease or greasy substances come in contact with oxygen under pressure. These substances must be kept away from oxygen regulators, cylinder valves, tubing and connections, and all other oxygen equipment.
- At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, mask selection and leak rate.

## 5. DESCRIPTION OF THE DEVICE

### 5.1 Package Contents

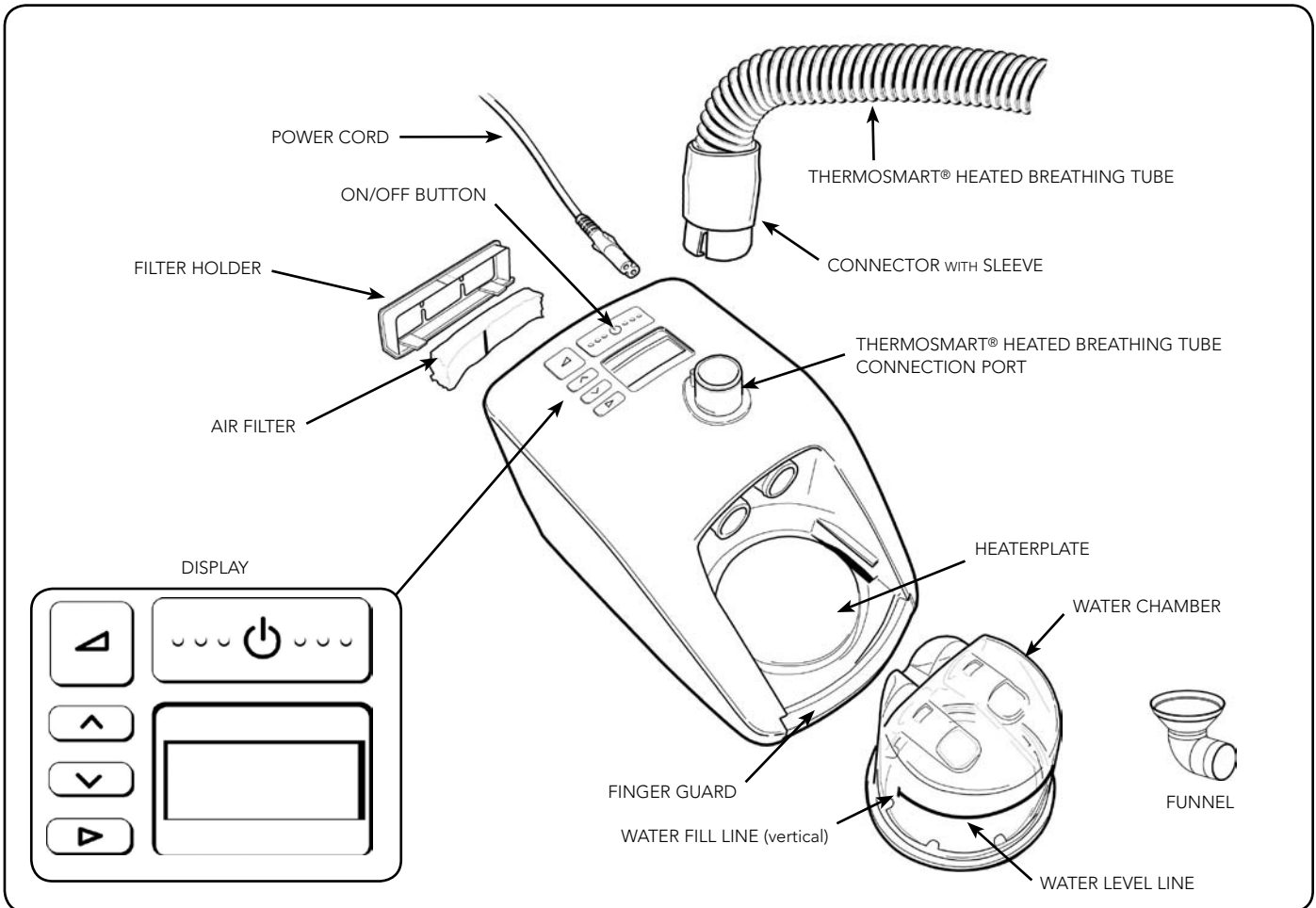


1 x SleepStyle™ 600 CPAP Series



Accessories

### 5.2 Important Parts of the Device



### 5.3 Accessories

|                 |                                      |                 |                                  |
|-----------------|--------------------------------------|-----------------|----------------------------------|
| <b>HC365</b>    | Standard Humidification Chamber      | <b>900HC232</b> | Compliance Download Serial Cable |
| <b>HC360*</b>   | Extended Life Humidification Chamber | <b>900HC607</b> | TitrationMaximizer™ Software     |
| <b>900HC522</b> | ThermoSmart® Heated Breathing Tube   | <b>900HC236</b> | Isolated Serial Adapter          |
| <b>900HC240</b> | Filter (2-Pack)                      | <b>900HC226</b> | Lead Extension Kit               |
| <b>900HC604</b> | Outlet Cleaning Kit HC600            | <b>900HC627</b> | Elbow Funnel (10-Pack)           |
| <b>900HC230</b> | ComplianceMaximizer™ Software        |                 |                                  |

**\*Not available in all countries**

## 5.4 ThermoSmart® Technology

This device has been designed for optimal patient comfort and offers the unique heated breathing tube technology ThermoSmart®. ThermoSmart® Technology allows for the delivery of optimal (higher and customized) levels of humidity to the patient, independent of ambient temperature.

This device can be adjusted on two levels to achieve optimal comfort:

**ThermoSmart® Humidity setting:** this setting regulates the temperature of the heater plate, adjusting the humidity levels for the comfort of the patient. Adjustment can be made from 1 to 4 with increments of 0.5. The device is preset to 2.5 which is suitable for most patients.

- If you experience dryness or find the air too cool: increase the setting
- If you find there is too much moisture in the tube or the air feels too hot: decrease the setting
- If you do not achieve optimal comfort with this setting further adjustments can be made by altering your ThermoSmart® Climate setting.

**ThermoSmart® Climate setting:** this setting provides further adjustment options to the humidity by increasing the temperature in the tube. Adjustment can be made from 1 to 3 with increments of 1. The device is preset to 2 which is suitable for most patients. Note, if the climate setting is adjusted, the humidity setting will revert back to the default setting.

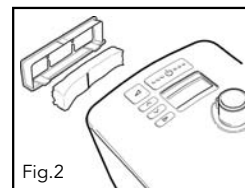
- ThermoSmart® Climate setting 3 is recommended for oral CPAP delivery.
- If you feel the range of settings offered by the ThermoSmart® Comfort setting are too dry or too cool: Increase the ThermoSmart® Climate setting.
- If you feel the range of settings offered by the ThermoSmart® Comfort setting are too warm or too humid: Reduce the ThermoSmart® Climate setting.

It is recommended to keep the (heated breathing) tube on top of bedding for the best humidity performance. To operate ThermoSmart® Humidity and Climate settings, refer to section 8 "Controls and Display" of this manual.

## 6. CLEANING AND MAINTENANCE

**PLEASE NOTE:** The device should be cleaned as required.

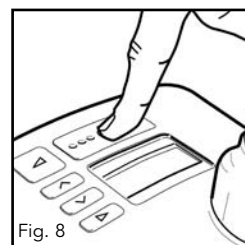
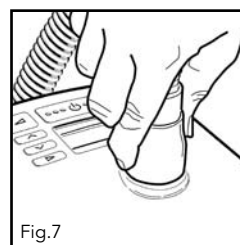
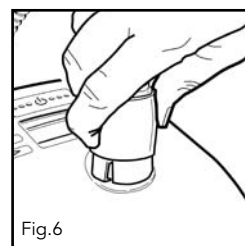
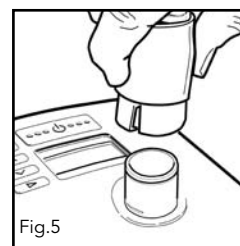
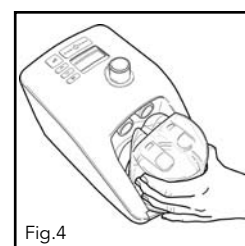
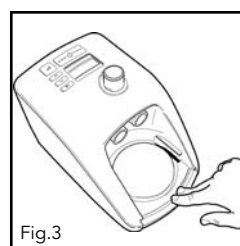
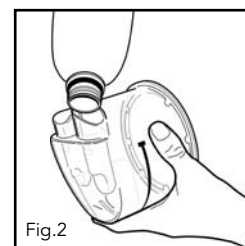
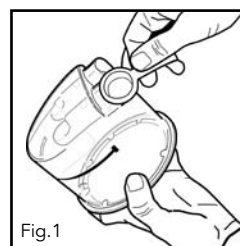
1. Switch off the device and unplug from the power socket.
2. Wipe the exterior of the device with a clean, damp (not wet) cloth and mild dishwashing detergent. Do not use harsh abrasives or solvents, or these may damage the device.
3. **DAILY**  
Clean chamber, heated breathing tube and heated breathing tube connection port.
  - Remove the heated breathing tube from the device by pulling sleeve upwards to unlock the connector. Then remove connector.
  - Wash the heated breathing tube with soapy water, rinse and then hang-up the heated breathing tube with its ends pointing to the floor to dry.
  - Remove the chamber by pushing down the finger guard and pulling out the chamber.
  - Pour out and discard the remaining water.
  - For standard (HC365) chambers, clean and wash with soapy water, then rinse and dry.
  - The extended life (HC360) chamber requires disassembly before cleaning. Push the base off the chamber top as shown in Fig. 1. Ensure the round seal at the base is not loose or damaged. Wash the chamber top and base in a mild dishwashing detergent. Rinse thoroughly and dry. This chamber may also be cleaned in a domestic dishwashing machine.
  - Thoroughly wipe the inside of the heated breathing tube connection port with a clean damp, low lint cloth.
4. **WEEKLY**  
Thoroughly clean the chamber.
  - Soak the inside of the chamber for 10 minutes in a solution of one part white vinegar to two parts water and rinse well with distilled water.
5. **MAINTENANCE**
  - Replace the air filter when it becomes significantly discoloured, at least once every three months or after 1000 hours machine run time. To do this, remove the filter holder from the back of the device as shown in Fig. 2. Ensure the vertical black line of the new filter is facing towards the device, and fit both back to the device.
  - Replace the chamber if it is cracked, discoloured or scratched.
  - Replace the heated breathing tube after 4000 hours usage or once per year. A damaged tube needs to be replaced immediately.



## 7. SETUP INSTRUCTIONS

When the chamber is fitted and filled, the device must remain upright, so that water cannot enter the enclosure.

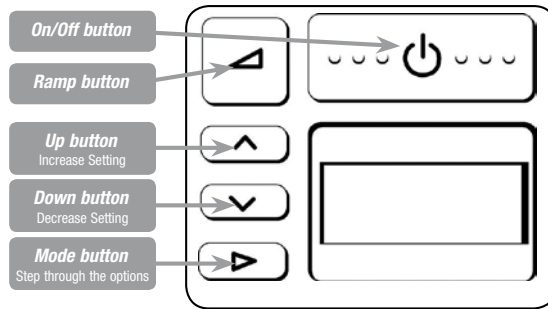
1. Remove your device from its packaging.
2. Place the device on a low shelf or on the floor beside your bed, the unit needs to be placed below head height.
3. Remove water chamber from the packaging.
4. Remove the blue caps and discard them (Fig.1).
5. Fill the chamber up to the water filling line with distilled water only (Fig.2).  
**Never fill the chamber through the heated breathing tube connector port. When moving your device, ensure that the water chamber is empty. Machine failure due to water damage is not covered by warranty.**
6. To attach the water chamber to the device, press down the finger guard and slide the chamber on (Figs 3 and 4).
7. When the chamber is fitted correctly, the finger guard will click into place.
8. One end of the heated breathing tube has a grey plastic connector. Lift the sleeve and slide connector on to the device. Push the sleeve down to lock (Figs 5, 6 and 7).
9. Connect the other end of the heated breathing tube to the mask.
10. Plug the device power cord into your household power socket.
11. Switch on the device by pressing the on/off button (Fig.8). The current ThermoSmart® Humidity setting is displayed.
12. For changing the setting refer to section 8 "Controls and Display".



**Your device is now ready for use.**

## 8. CONTROLS AND DISPLAY

### 8.1 Display Description and Functions



| KEY | FUNCTION & DESCRIPTION   | OPERATION   |
|-----|--|---|
|     | <b>ON/OFF</b><br>Switches the device ON and OFF  | <b>TO SWITCH "ON"</b> <ul style="list-style-type: none"> <li>Press  button down briefly.</li> <li>The device will default to display the ThermoSmart® Humidity setting.</li> </ul> <b>TO SWITCH "OFF"</b> <ul style="list-style-type: none"> <li>Remove your mask</li> <li>Press  button briefly</li> </ul> |
|     | <b>RAMP</b><br>Reduces pressure to a lower level to help you fall asleep. The pressure will gradually return to full operating pressure over 20 minutes. | <b>TO SWITCH "ON"</b> <ul style="list-style-type: none"> <li>Press </li> <li>(NB: to reset ramp during a cycle the device must be switched off first)</li> </ul> <b>TO SWITCH "OFF"</b> <ul style="list-style-type: none"> <li>Press </li> </ul>  |
|     | <b>INCREASE/DECREASE</b><br>Adjusts settings up or down  | <ul style="list-style-type: none"> <li>Press  and  button to raise or lower settings.</li> </ul>  |
|     | <b>MODE</b><br>To step through options.  | <ul style="list-style-type: none"> <li>Press sequentially to step through and view options available.</li> </ul>  |

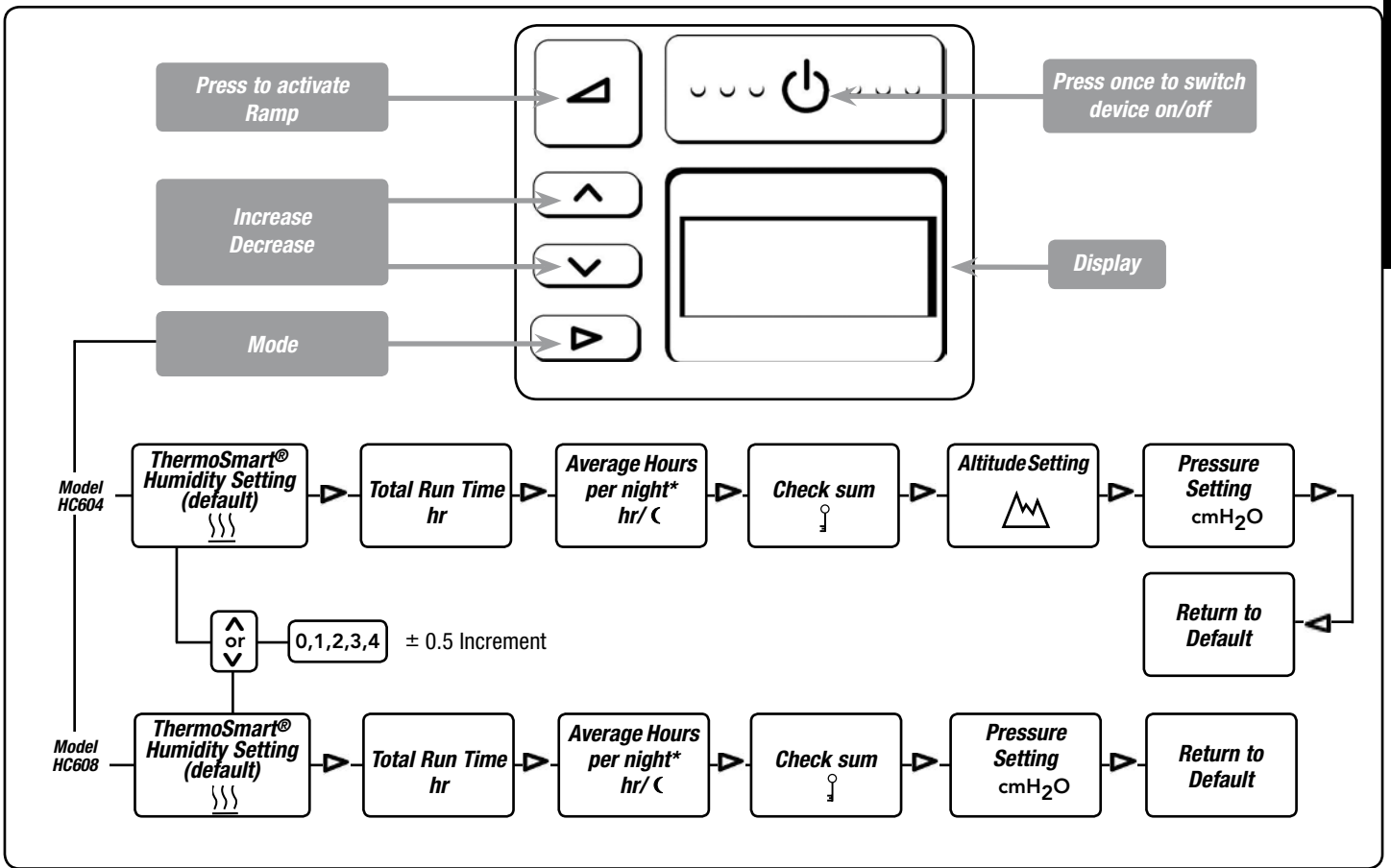
| PATIENT MENU   | DISPLAY            | OPERATION   |
|--|--------------------|---|
| For viewing CPAP settings, humidity, compliance data, altitude and pressure settings |                    | <b>TO VIEW ITEMS</b><br>Press  key to sequentially view: <ul style="list-style-type: none"> <li><b>ThermoSmart® Humidity setting (default display)</b><br/>For adjusting ThermoSmart® Humidity setting levels to minimize upper airway side effects from CPAP use.<br/>Press  and  button to raise or lower settings</li> </ul> |
|  | hr                 | <ul style="list-style-type: none"> <li><b>Total run hours:</b> displays the total number of hours the device has been switched on (includes hours without mask use)</li> </ul>  |
|  | hr/☾               | <ul style="list-style-type: none"> <li><b>Average compliance hours per night:</b> displays average number of hours the device has been used at night with the mask on.</li> </ul>   |
|  |                    | <ul style="list-style-type: none"> <li><b>Check sum:</b> displays information for the medical practitioner or the dealer to check compliance.</li> </ul>  |
|  |                    | <ul style="list-style-type: none"> <li><b>Altitude setting:</b> displays altitude setting. Press  or  to change altitude.</li> </ul>  |
|  | cmH <sub>2</sub> O | <ul style="list-style-type: none"> <li><b>Pressure setting:</b> displays pressure setting.</li> </ul>   |

| PATIENT MENU - Additional Settings   | DISPLAY            | OPERATION  |
|--|--------------------|--|
| To access additional settings:<br>From the Default setting "THERMOSMART® HUMIDITY"<br>Press the  key for 3 seconds |                    | <ul style="list-style-type: none"> <li><b>ThermoSmart® Climate setting*</b><br/>To change the delivered temperature: Press  for warmer more humid air delivery. Press  for cooler and drier air delivery.* Refer to Section 5.4</li> </ul> |
|  |                    | <ul style="list-style-type: none"> <li><b>Altitude</b><br/>Select "m" for metres or "ft" for feet using  and  keys.</li> </ul>   |
|  | 3000               | <ul style="list-style-type: none"> <li><b>Altitude setting</b><br/>- Set the altitude level by pressing  and  keys<br/>- Press  to exit menu</li> </ul>  |
|  | cmH <sub>2</sub> O | <ul style="list-style-type: none"> <li><b>Actual Pressure</b> (Displays actual pressure)<br/>- Display reverts to default if the menu is not exited. Press  button in order to exit menu (only available in HC602).</li> </ul>             |

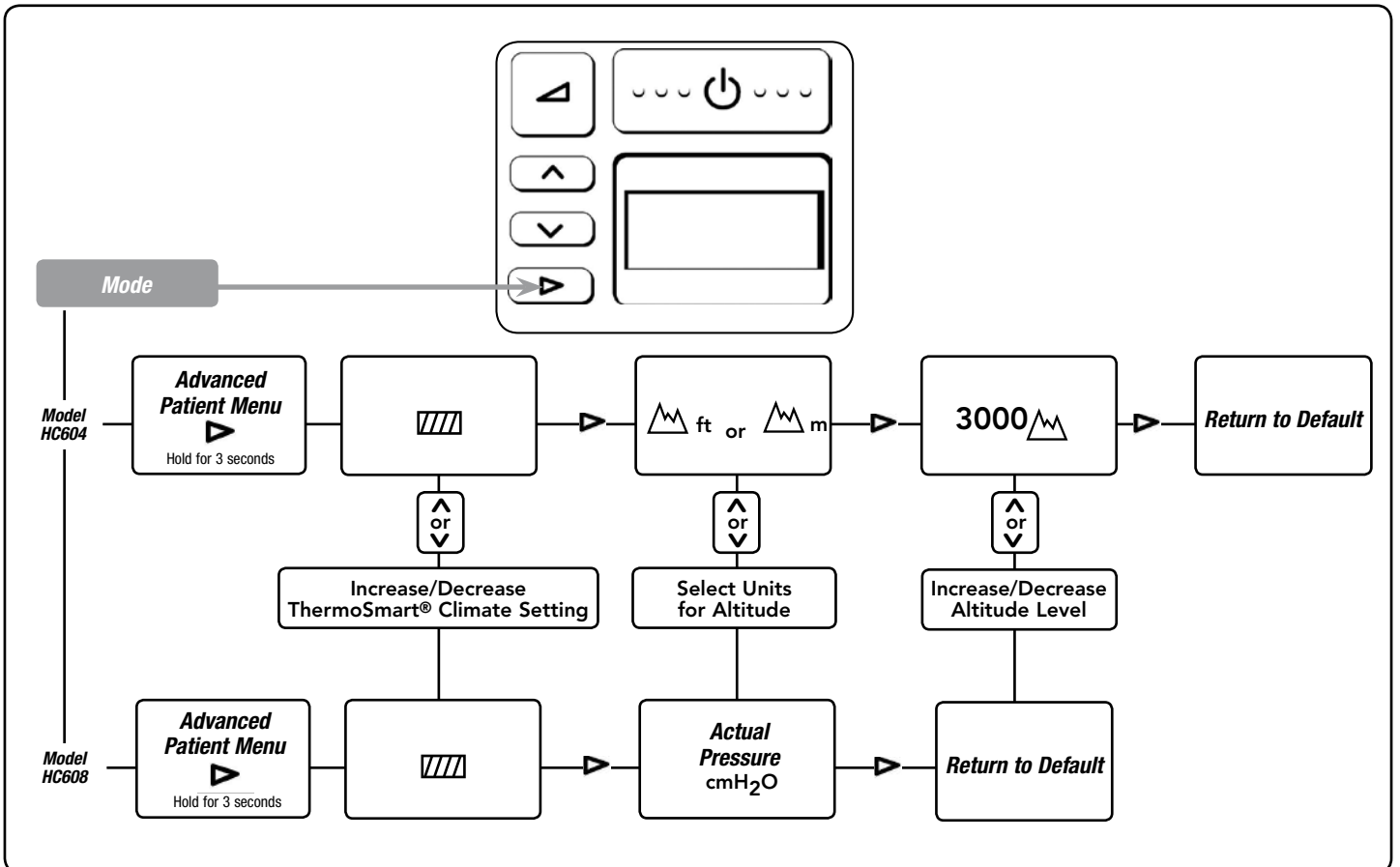
**Warning:** Failure to select correct altitude setting (for any given location) will have an adverse effect on delivered pressure.

● \* When the ThermoSmart® Climate setting is altered the Humidity Setting will revert back to default setting 2.5

## 8.2 Patient Menu Summary



## 8.3 Patient Menu - Additional Settings Summary



• **Warning:** Failure to select correct altitude setting (for any given location) will have an adverse effect on delivered pressure.



## 9. FREQUENTLY ASKED QUESTIONS

### Do I have to use distilled water with my device?

The use of distilled water will maximize the life of the water chamber. Water from the faucet will often contain minerals which can damage the chamber, causing pitting in the base, even if the water is passed through a filter.

### Can I use my device in other countries?

Yes. Simply use the appropriate electrical socket adaptor and the device will automatically adapt to any voltage supply.

Note: When moving your device, ensure that the water chamber is empty. Machine failure due to water damage is not covered by warranty.

### Can I use supplemental oxygen with my device?

Yes, oxygen can be administered at the mask. Turn the device on before turning on the oxygen. Ensure that the oxygen source is turned off before turning off the device to avoid oxygen accumulating in the machine.

### When do I replace my water chamber?

Replace the chamber if the plastic walls of the chamber become cracked or cloudy or the chamber base becomes pitted.

(Note: If the chamber leaks at all, it should be replaced immediately).

### Can I use my device without a heated breathing tube?

Yes you can, but you will not gain the optimum humidity performance the device offers.

The device will then not display the heated breathing tube symbol and show the following display:



## 10. PRODUCT SPECIFICATIONS

|   |   |
|---|---|
| <b>DIMENSIONS:</b>                              | 273 mm x 170 mm x 175 mm<br>(10.7" x 6.7" x 6.9")   |
| <b>WEIGHT:</b>                                  | 2.1 kg (4.6 lbs) unit only<br>3.4 kg (7.5 lbs) packaged in<br>bag incl. accessories                               |
| <b>ELECTRICAL RATINGS</b>                       |   |
| Supply Frequency:                               | 50-60 Hz  |
| Supply Voltage and Current:                     | 100-115 V (1.5 A, max 1.7 A),<br>220-240 V (1.0 A, max 2.0 A)<br>Note: These values represent<br>average current. |
| <b>DC to AC Inverter<br/>requirements:</b>      | 115 V - 200 W/300 W surge<br>230 V - 300 W/500 W surge  |
| <b>Heater Plate:</b>                            | max. 85 W   |
| <b>Heater Plate Temperature:</b>                | max. 65 °C (149 °F)   |
| <b>Heated breathing tube<br/>Power Setting:</b> | max. 30 W   |
| <b>PERFORMANCE</b>                              |   |
| Pressure Range:                                 | 4 to 20 cmH <sub>2</sub> O  |
| Altitude Range:                                 | 0 to 3000 m, or 0 to 9000 ft  |
| Warm-up time:                                   | 30 min  |
| Humidity delivered:                             | 30 mg/l*  |

\*measured at 22 °C ambient temperature: 10 cmH<sub>2</sub>O at bias flow.

### STANDARDS COMPLIANCE:

Designed to conform to the

requirements of:

IEC 60601-1  
UL60601-1  
CSA C22.2/No. 601.1  
AS3200.1.0  
EN60601-1

The device complies with the electromagnetic compatibility requirements of IEC 60601-1-2. In certain circumstances, the device may affect or be affected by nearby equipment due to the effects of electromagnetic interference. If this should happen, try moving your unit or the location of the device causing interference, or alternatively consult your homecare provider.

## 11. OPERATING CONDITIONS

|                             |                      |
|-----------------------------|----------------------|
| <b>AMBIENT TEMPERATURE:</b> | 5 - 35 °C            |
| <b>HUMIDITY:</b>            | 10 - 95% RH          |
| <b>ALTITUDE:</b>            | 0 - 3000 m (9000 ft) |

Above 1500 m (4500 ft) the maximum operating pressure will be reduced.

## 12. STORAGE AND TRANSPORT CONDITIONS

The device should be stored and transported in environmental conditions of: 14 to 140 °F (-10 to 60 °C).

## 13. TROUBLESHOOTING

If you feel that your device is not operating correctly, consult your homecare dealer. Do not attempt to repair the device yourself.

**Fisher & Paykel Healthcare have a policy of continued product improvement and reserve the right to alter specifications without notice.**

## 14. WARRANTY

Please contact your Fisher & Paykel Healthcare Provider regarding warranty.

## 15. APPENDIX

The following table lists the main difference in features across the SleepStyle™ 600 Product Range.

| MODEL | Fully Integrated CPAP with Heated Humidification | Patient Compliance Monitoring (LCD & Download) | Auto Altitude Adjustment/ Leak Compensation |
|-------|--|--|---|
| HC604 | ✓  | ✓  | -   |
| HC608 | ✓  | ✓  | ✓   |

NOTE:

- All models are fully integrated with ThermoSmart® Technology
- Some models are not available for sale in all countries.

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